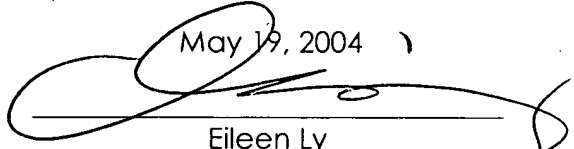




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Patent Docket P1469R1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Yvonne Man-yee Chen et al.  Serial No.: 10/624,153  Filed: July 21, 2003  For: ANTIBODY VARIANTS	Group Art Unit: 1641  Examiner: To Be Assigned  Confirmation No: 2413  CUSTOMER NO: 09157  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on  May 19, 2004   Eileen Ly
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR § 1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.

☐ **37 CFR § 1.97(c)**

- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes

prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because **a)**[X] they were previously cited by or submitted to the Office in a prior application Serial No. 09/440,781, filed 16 November 1999 and relied upon in this application for an earlier filing date under 35 USC §120 **and/or** because **b)**[X] this application was filed after June 30, 2003. Applicants are no longer required to submit copies of U.S. patents and U.S. patent application publications cited in information disclosure statements for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the

national stage under 35 USC §371 after June 30, 2003 (**1276 OG 55**). Nevertheless, applicants stand ready to provide copies at the request of the Examiner.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

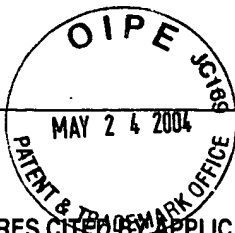
Date: May 19, 2004

By: 

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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1469R1C1

Serial No.

10/624,153

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Yvonne Chen et al.

Filing Date

21 Jul 2003

Group

1641

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	5,821,337	13.10.98	Carter et al.			
	* 2	6,010,861	04.01.00	Blume, A.			
	* 3	6,037,454	14.03.00	Jardieu et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	* 4	2,125,240	07.12.95	CANADA				
	* 5	91-40386	03.06.97	JAPAN (ABSTRACT ONLY)				
	* 6	WO 97/31024	28.08.97	PCT				
	* 7	WO 98/23746	04.06.98	PCT				
	* 8	WO 98/23761	04.06.98	PCT				
	* 9	WO 98/45331	15.10.98	PCT				
	*10	WO 98/45332	15.10.98	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	*11	Amit et al., "Three-Dimensional Structure of an Antigen-Antibody Complex at 2.8 Å Resolution" <u>Science</u> 233:747-753 (Aug 1986)
	*12	Balint and Larrick, "Antibody engineering by parsimonious mutagenesis" <u>Gene</u> 137(1):109-118 (Dec 27, 1993)
	*13	Barbas III et al., "In Vitro Evolution of a Neutralizing Human Antibody to Human Immunodeficiency Virus Type 1 to Enhance Affinity and Broaden Strain Cross-Reactivity." <u>Proc. Natl. Acad. Sci. USA</u> 91(9):3809-3813 (Apr 26, 1994)
	*14	Brunger et al., "Crystallographic R factor refinement by molecular dynamics" <u>Science</u> 235:458-460 (Jan 23, 1987)
	*15	Chiswell and McCafferty, "Phage antibodies: will new 'coliclonal' antibodies replace monoclonal antibodies?" <u>Trends In Biotechnology</u> 10(3):80-84 (Mar 1992)
	*16	Fenney and Thuerauf, "Sequence and fine specificity analysis of primary 511 anti-phosphorylcholine antibodies" <u>Journal of Immunology</u> 143(12):4061-4068 (Dec 15, 1989)
	*17	Gazzano-Santoro et al., "A Non-Radioactive Complement-Dependent Cytotoxicity Assay for Anti-CD20 Monoclonal Antibody." <u>Journal of Immunological Methods</u> 202:163-171 (1997)
	*18	Groves et al., "Production of an ovine monoclonal antibody to testosterone by an interspecies fusion" <u>Hybridoma</u> 6(1):71-76 (Feb 1987)
	*19	Hawkins et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation" <u>J. Mol. Biol.</u> 226:889-896 (1992)
	*20	Jones et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those From a Mouse." <u>Nature</u> 321:522-525 (May 29, 1986)
	*21	Kabat. <u>Sequences of Proteins of Immunological Interest</u> , US Dept of Health and Human Services, NIH, 5th edition, Bethesda, MD (1991)
	*22	LeBlanc et al., "Recognition properties of a sequence-specific DNA binding antibody" <u>Biochemistry</u> 37(17):6015-6022 (Apr 28, 1998)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1469R1C1	Serial No. 10/624,153
<b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicant Yvonne Chen et al.	
				Filing Date 21 Jul 2003	Group 1641
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
	*23	Lee et al., "Strong inhibition of fibrinogen binding to platelet receptor $\alpha_{IIb}\beta_3$ by RGD sequences installed into a presentation scaffold" <u>Protein Engineering</u> 6(7):745-754 (Sep 1993)			
	*24	McLane et al., "Transplantation of a 17-amino acid $\alpha$ -helical DNA-binding domain into an antibody molecule confers sequence-dependent DNA recognition" <u>Proc. Natl. Acad. Sci. USA</u> 92(11):5214-5218 (May 23, 1995)			
	*25	Muller et al., "VEGF and the Fab fragment of a humanized neutralizing antibody: crystal structure of the complex at 2.4 Å resolution and mutational analysis of the interface" <u>Structure</u> 6(9):1153-1167 (Sep 15, 1998)			
	*26	Ohlin and Borrebaeck, "Insertions and deletions in hypervariable loops of antibody heavy chains contribute to molecular diversity" <u>Molecular Immunology</u> 35(4):233-238 (Mar 1998)			
	*27	Panka et al., "Variable region framework differences result in decreased or increased affinity of variant anti-digoxin antibodies" <u>Proc. Natl. Acad. Sci. USA</u> 85:3080-3084 (May 1988)			
	*28	Presta et al., "Humanization of an Anti-Vascular Endothelial Growth Factor Monoclonal Antibody for the Therapy of Solid Tumors and Other Disorders" <u>Cancer Research</u> 57(20):4593-4599 (Oct 15, 1997)			
	*29	Rader and Barbas III, "Phage display of combinatorial antibody libraries" <u>Current Opinion in Biotechnology</u> 8(4):503-508 (Aug 1997)			
	*30	Rudikoff et al., "Single amino acid substitution altering antigen-binding specificity" <u>Proc. Natl. Acad. Sci. USA</u> 79:1979-1983 (1982)			
	*31	Schier et al., "Isolation of picomolar affinity anti-c-erbB-2 single-chain Fv by molecular evolution of the complementarity determining regions in the center of the antibody binding site" <u>Journal of Molecular Biology</u> 263(4):551-567 (Nov 8, 1996)			
	*32	Sheets et al., "Efficient construction of a large nonimmune phage antibody library: the production of high-affinity human single-chain antibodies to protein antigens" <u>Proc. Natl. Acad. Sci. USA</u> 95(11):6157-6162 (May 26, 1998)			
	*33	Simon and Rajewsky, "A functional antibody mutant with an insertion in the framework region 3 loop of the V <sub>H</sub> domain: implications for antibody engineering" <u>Protein Engineering</u> 5(3):229-234 (Apr 1992)			
	*34	Thompson et al., "Affinity maturation of a high-affinity human monoclonal antibody against the third hypervariable loop of human immunodeficiency virus: use of phage display to improve affinity and broaden strain reactivity" <u>Journal of Molecular Biology</u> 256(1):77-88 (Feb 16, 1996)			
	*35	Wilson et al., "Somatic hypermutation introduces insertions and deletions into immunoglobulin V genes" <u>Journal of Experimental Medicine</u> 187(1):59-70 (Jan 5, 1998)			
	*36	Wu et al., "Stepwise in vitro affinity maturation of Vitaxin, an $\alpha_v\beta_3$ -specific humanized mAb" <u>Proc. Natl. Acad. Sci. USA</u> 95(11):6037-6042 (May 26, 1998)			
	*37	Yang et al., "CDR walking mutagenesis for the affinity maturation of a potent human anti-HIV-1 antibody into the picomolar range" <u>Journal of Molecular Biology</u> 254(3):392-403 (Dec 1, 1995)			
	*38	Zhao et al., "A paradigm for drug discovery using a conformation from the crystal structure of a presentation scaffold" <u>Nature Structural Biology</u> 2(12):1131-1137 (Dec 1995)			
Examiner			Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					